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10/582,450

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Shozo Tanada

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EXAMINER

CHAWLA, JYOTI

ART UNIT

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1781

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/582,450 | Applicant(s) TANADA ET AL. | |
| | Examiner JYOTI CHAWLA | Art Unit 1794 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/8/06, 4/30/07 and 1/11/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary amendment to claims 1-10 and addition of claims 11-12, dated 2/19/2008 is received . Claims 1-12 are pending and are examined in the current application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 provides for the use of “a puree or a fruit juice obtained from acerola fruit”, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Correction is required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A) Claims 1-2 and 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (EP 5071571, English abstract), hereinafter Fuchs, in view of the combination of IDS reference to Nair et al (WO 01/15553 A1), hereinafter Nair, and Oita (with English abstract).

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Fuchs et al , hereinafter Fuchs discloses of beverage comprising acerola puree (English abstract), as claimed. Fuchs does not disclose the compounds present in acerola product, however, Nair discloses that fruits, including acerola comprise of phytochemicals, such as flavonoids, polyphenols including anthocyanins, anthocyanadins (hydrolyzed anthocyanins), cyanindins etc.(Nair, Page 3, lines 1-3 and 20-26, page 10, lines 1-12, Page 10, lines 22 to page 11, line 20). Further, polyphenols which have been known to show inhibitory activity thermo tolerant bacteria (*Alicyclobacillus acidoterrestris*), as disclosed by IDS document by Oita (see English Abstract) wherein Oita discloses of polyphenolic compounds found in grape varieties. However, fruits including Acerola also contain polyphenols including anthocyanins, anthocyanadins (hydrolyzed anthocyanins), flavonoids, cyanindins etc, as disclosed by Nair (Nair, Page 3, lines 1-3 and 20-26, Page 10, lines 6-12, Page 10, lines 22 to page 11, line 20).

Thus, product as disclosed by Fuchs comprises a puree or a fruit juice containing polyphenolic compounds. The aspect of inhibiting thermo tolerant bacteria is a feature of the polyphenols as shown by the Oita abstract. Thus, at the time of the invention one of ordinary skill in the art was aware that polyphenols have inhibitory activity towards thermo tolerant bacteria *Alicyclobacillus*. It was also known that food products containing Acerola fruit, its juice, puree etc contain polyphenols (Fuchs and Nair). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that polyphenols from Acerola pulp will be present in the beverage disclosed by Fuchs, and that the polyphenols of the beverage will exhibit an inhibitory effect on the growth of thermo tolerant bacteria to a certain extent. One of ordinary skill would have been motivated to modify Fuchs and disclose the polyphenolic compounds at least for the purpose of educating the consumer about additional beneficial effects of the beverage.

Regarding claim 2, Fuchs abstract is silent about the acerola fruit substance being “a dried substance”. However, Nair discloses of making dry fruit extracts (Page 15, 20-30, also see page 16). Thus, dried fruit and vegetable extracts were well known in the art at

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the time of the invention (Nair, pages 11-16) for their long shelf life and ease of storage. Therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to modify Fuchs and make a beverage composition comprising dried Acerola component. One of ordinary skill would have been motivated to do so at least for the purpose of achieving a beverage comprising acerola with a longer shelf life.

The limitation of claims 4, 5 and 11, reciting thermo acidophilic bacilli (TAB) of genus *Alicyclobacillus acidoterrestris*, has already been discussed above in claim 1.

Regarding claims 6-10, Fuchs discloses of making a fruit drink comprising acerola puree or juice, and regarding the specific and the limitation of "inhibiting or blocking bacterial growth" has already been discussed above regarding claim 1.

Further, regarding the limitation of making a product that "is to be added to food or drink", as recited in claim 12, Fuchs teaches of a beverage, which is a food or drink comprising acerola (i.e., bacteriostatic agent, as discussed above regarding claim 1), however, addition of dried extracts to foods and beverages was well known in the art at the time of the invention. For example, Fuchs, discloses of enriching the drink with minerals like trisodium phosphate etc., (abstract and title), i.e., adding minerals. Further, Nair discloses that the composition comprising fruit flavonoids, may be formulated into a gel, a capsule, a tablet, a syrup, a beverage or a powder suitable to use as a dietary food supplement (Page 3, 27-29 and page 16, lines 23-27). Thus, dietary ingredients that can be added to foods and beverages to enhance the taste or flavor or nutrient content of the food was notoriously well known, e.g., sprinkling sugar on fruit or in tea/coffee. Therefore, it would have been well within the purview of one of ordinary skill to modify Fuchs and make acerola component as dried product, which can be added to food or drink (as discussed above regarding claim 2). One of ordinary skill would have been motivated to modify Fuchs at least for the purpose of providing a nutritive ingredient in a shelf stable form that can be added to foods and drink at the time of

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consumption in desired amount based on the nutrition and organoleptic experience desired.

B) Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs, Nair and Oita further in view of Shanbrom (WO 99/13889), hereinafter Shanbrom.

Claims 1-2, 4-12 have been rejected over Fuchs, in view of the combination of and Nair and Oita above.

Fuchs teaches of a beverage comprising acerola puree or juice, as disclosed in claim 1, however is silent as to the puree or the fruit juice being “desugared”. Desugaring fruits to remove juices and sugars was well known in the art at the time of the invention. Nair discloses that during extraction, juice of fruits may be separated from the pulp (Page 14, lines 3-20). Shanbrom discloses of extracting colors (anthocyanins) and antibacterial and antifungal compound from cranberry press cake, which is waste product left after juice has been extracted (Page 3, summary of invention). Thus, making dried products from desugared fruits was well known in the art at the time of the invention and it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to modify Fuchs and utilize a desugared Acerola component, at least for the purpose of obtaining the fibrous and phenolic components from the fruit without any of the high calorie sugar. One of ordinary skill would have been motivated to do so at least for the purpose of utilizing an inexpensive and low calorie ingredient to create a beverage having good nutritional components.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
Examiner
Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794